IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.	:	09/760,136	:	Confirmation No. 2264
Applicant	:	Stephen Nuss		
Filed	:	January 12, 2001		
TC/A.U.	:	3736		
Examiner	:	Foreman, Jonathan M.		
Our Docket No.	:	990356.CON		
Customer No.	:	23595		

Mail Stop Non-Fee Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. §132

I, Dr. Jeffrey W. Chambers, declare and say as follows:

1. I have reviewed and incorporate by reference the averments set out in my Declaration of April 10, 2004, previously submitted in the prosecution of the subject application.

2. I am informed that claims 12, 16-20 and 24-27 have again been rejected under 35 U.S.C. §103(a) as being directed to an invention that would have been obvious at the time it was made to persons of ordinary skill in the art from what is taught by U.S. Patent 4,776,330 to Chapman et al. when considered in view of U.S. Patent 6,132,389 to Cornish et al. For reasons and facts presented herein below, I respectfully disagree with such a conclusion.

3. I consider myself to be a person of ordinary skill in the art of designing, producing and testing guidewires used in intravascular procedures. Support for this position is set out in my April 10, 2004 Declaration.

4. I have read and thoroughly considered the teachings of the cited Chapman et al. and Cornish et al. patents and nothing in these two patents would lead one skilled in the art to conceive and develop an intravascular guidewire for use in catheterization procedures, such as in performing angiography and balloon angioplasty that is made by appropriately grinding and shaping a wire of titanium, molybdenum, zirconium and tin

(Ti, Mb, Zr, Sn) alloy. This opinion is based principally on the fact that neither of the cited patents expressly discloses the use of this alloy as a suitable vascular guidewire material. The Chapman et al. reference discloses a kit whose components are used to treat fractures of the femur bone and that are preferably fabricated from Ti, Mb, Zr, Sn alloy because this alloy is "inert" and "resilient". Neither of these properties is of particular advantage in fabrication of intravascular guidewires. As stated in my Declaration of April 20, 2004, tissue sensitivity is not an issue, given the short time that a vascular guidewire remains in a patient.

5. I have noted that Chapman et al. describes the use of a "guidewire" in supporting/guiding a reamer used to core out a cylindrical bore in the bone and to insert an anchor in the bore, but such guidewire would only be 10"-12" long and need not navigate any bends or curves. Hence, even if assuming arguendo, the guidewire in the Chapman et al. patent were made of Ti, Mb, Zr, Sn alloy, it would not in any way suggest to one skilled in the art that the alloy would lend itself to an intravascular guidewire that is typically 90"-120" in length and that must have acceptable pushability, torqueability and a malleability characteristics that will allow it to be advanced through the vascular system from an area in the groin to a target cardiac blood vessel.

6. The Chapman et al. patent repeatedly identifies fracture-stabilizing kit components formed from Ti, Mb, Zr, Sn. See "Abstract" and col. 2, lines 31-46, col. 3, lines 21-23; col. 3, lines 33-58; col. 4, lines 34-65. In no instance is a guidewire identified as a kit component to be made from this alloy. While a "guidewire" is mentioned several times in the patent, it is silent as far as identifying the material from which it is made.

7. I have considered the paragraph beginning at col. 13, line 36, and it does not lead me to conclude that the guidewire 25 must be made from a Ti, Mb, Zr, Sn alloy merely because it may be left in the patient along with other components made of that alloy. In that at col. 17, lines 20-24 of the specification, it is stated that "conventional fixation pins" can be implanted, it suggests to me that components, other than those made of Ti, Mb, Zr, Sn, can be used in conjunction with kit components that are made of this alloy. This being the case, I see no reason to conclude that the guidewire described in the

Chapman et al. patent, but not identified as a kit component, must be of the Ti, Mb, Zr, Sn alloy.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the Unites States Code, and that such willful false statements may jeopardize the validity of the above-references application or any patent issuing thereon.

Dated: July 1, 2005.

Dr. Jeffory W. Chambers